

EPA REGISTRATION NUMBER 84229-5



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

84229-5

Date of Issuance:

AUG 7 2008

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Triadimefon Technical

Name and Address of Registrant (include ZIP Code):

Tide International USA, Inc.
21 Hubble
Irvine, CA 92618

c/o Ann M. Tillman
Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

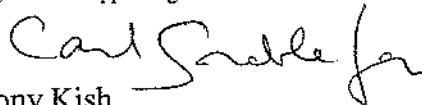
This product is conditionally registered in accordance with FIFRA sec. 3(c)(7) (A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. You must submit two copies of a final printed label within 45 days from the date of this notice which makes the following changes:

A. EPA registration number must read 84229-5.

Signature of Approving Official:


Tony Kish
Product Manager Team 22
Fungicide Branch
Registration Division (7505P)

Date:

AUG 7 2008

B. On page 2 in the Directions for Use Section change "USEPA" to read "US EPA."

The Agency has reviewed the product chemistry data submitted for the above mentioned product and has concluded that:


1. The proposed basic CSF (dated 1/14/08 for technical formulation was reviewed and found to be acceptable.
2. The proposed basic MUP is not substantially similar to the cited product because of differences in the label text and impurity profile.
3. The product chemistry data submitted for the guidelines 830 Series Group A and Group B, with the exception of storage stability (830.6317) and corrosion characteristics (830.6320), are acceptable.
4. You must submit a one year GLP storage stability (830.6317) and corrosion characteristics (830.320) data. It is recommended that the observations be made at 0, 3, 6, 9 and 12 month intervals. The results must be submitted to the Agency in the electronic format as well as a hard copy by November 1, 2009.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Note that you will soon receive generic data call in (GDCI) from the Agency which includes all generic data required in the Tridimefon RED. This registration is granted subject to satisfaction of the GDCI.

A copy of the label stamped "Accepted with comments" is enclosed for your records.

Sincerely,


Tony Kish,
Product Manager Team 22,
Fungicide Branch
Registration Division (7505P)

Enclosures

2

Triadimefon Technical

FOR MANUFACTURING USE ONLY

ACTIVE INGREDIENT:

Triadimefon:..... 99.0%

OTHER INGREDIENTS:..... 1.0%**TOTAL:**..... 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN	
There is no specific antidote. Treat symptomatically. This compound does not cause any definite symptoms that would be diagnostic. Poisoning is accompanied by hyperactivity followed by sedation.	
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 for emergency medical treatment information.	

EPA Reg. No. 84229-
EPA Est. No.Manufactured for:
Tide International USA, Inc.
21 Hubble
Irvine, CA 92618ACCEPTED
with COMMENTS
In EPA Letter Dated

Net Weight:

AUG 7 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

84229-5

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed, absorbed through skin, inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a fungicide for the following use(s):

(1) golf course turfgrass, sod farm turfgrass, outdoor- and greenhouse-grown ornamentals (trees, shrubs, flowering plants, including roses), azaleas (for control of pine-twisting rust only), pine trees (including Christmas trees), pine seedlings, pine seed, and pineapple (pre-plant dip and postharvest dip only);

(2) uses for which USEPA has accepted the required data or citations of data that the formulator has submitted in support of registration, and

(3) uses for experimental purposes that are in compliance with USEPA requirements.

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place away from food, drink and animal feeding stuffs. Store in original container and out of reach of children, preferable in a locked storage area. If product spills or container leaks, carefully sweep and collect material into a pile. Follow directions below for disposal.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into processing equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. Offer the drum for recycling, if available.

CONDITION OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully.

Tide International USA, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Tide International USA, Inc., and Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, TIDE INTERNATIONAL USA, INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

To the extent consistent with applicable law, neither Tide International USA, Inc. nor Seller shall be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF TIDE INTERNATIONAL USA, INC. AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF TIDE INTERNATIONAL USA, INC. OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Tide International USA, Inc. and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Tide International USA, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Tide International USA, Inc. c/o Pyxis Regulatory Consulting 411C 136th St. NW Gig Harbor, WA 98332	EPA Registration Number/File Symbol 84229-L
Active Ingredient(s) and/or representative test compound(s) Triadimefon	Date July 23, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non-food crop; Greenhouse non-food	Product Name Triadimefon Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Ann M. Tillman

Date

7/23/08

Typed or Printed Name and Title

Ann M. Tillman, Agent

3/31/08 & 22

XX	XX	GIG HARBOR, WA 98332
COMPANY#	081959	PYXIS REGULATORY CONSULTING, INC.
* DATA TYPES *		Agent for: ETIGRA LLC
EU AT EC FW EF OT		4110 136TH ST, NW
XX	XX	GIG HARBOR, WA 98332
COMPANY#	083558	MANA, INC
* DATA TYPES *		Agent for: CELSIUS PROPERTY, BV (NEUHASE
EU AT EC FW EF OT		4515 FALLS OF NEUSE RD., SUITE 300
XX	XX	RALEIGH, NC 27609
COMPANY#	084653	GENERIC ENDANGERED SPECIES TASK FORCE (GESTF)
* DATA TYPES *		500 EIGHTH STREET, NW
EU AT EC FW EF OT		WASHINGTON, DC 20004
XX		

Get Revised matrix
and Certificate adding
Lampson Coys.

CHEMICAL CHEMICAL NAME
109901 Triadimefon

COMPANY#	000264	BAYER CROPSCIENCE LP
* DATA TYPES *		2 T.W. ALEXANDER DRIVE
EU AT EC FW EF OT		RESEARCH TRIANGLE PARK, NC 27709
XX		
COMPANY#	000432	BAYER ENVIRONMENTAL SCIENCE
* DATA TYPES *		A BUSINESS GROUP OF BAYER CROPSCIENCE LP
EU AT EC FW EF OT		PO BOX 12014
XX	XX	RESEARCH TRIANGLE PARK, NC 27709
COMPANY#	003125	BAYER CORP
* DATA TYPES *		PO BOX 4913
EU AT EC FW EF OT		KANSAS CITY, MO 641200013
XX		
COMPANY#	009198	THE ANDERSONS LAWN FERTILIZER DIVISION, INC.
* DATA TYPES *		DBA/ FREE FLOW FERTILIZER
EU AT EC FW EF OT		PO BOX 119
XX	XX	MAUMEE, OH 43537

COMPANY#	039967	LANXESS CORPORATION
* DATA TYPES *		111 RIDC PARK WEST DRIVE
EU AT EC FW EF OT		PITTSBURGH, PA 15275
XX	XX	

missing

FROM MATRIX

COMPANY#	047629	WOODSTREAM CORP.
* DATA TYPES *		PO BOX 327
EU AT EC FW EF OT		LITITZ, PA 17543
XX	XX	XX
COMPANY#	066607	SPRAY DRIFT TASK FORCE
* DATA TYPES *		1900 K STREET, NW
EU AT EC FW EF OT		WASHINGTON, DC 20006
XX		
COMPANY#	071754	OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE, L.L.C.
* DATA TYPES *		1350 I STREET, N.W.
EU AT EC FW EF OT		WASHINGTON, DC 20005
XX		
COMPANY#	071755	AGRICULTURAL REENTRY TASK FORCE
* DATA TYPES *		1350 I STREET, N.W.
EU AT EC FW EF OT		WASHINGTON, DC 20005
XX		
COMPANY#	072155	BAYER ADVANCED
* DATA TYPES *		A BUSINESS UNIT OF BAYER CROPSCIENCE LP
EU AT EC FW EF OT		PO BOX 12014
XX	XX	RESEARCH TRIANGLE PARK, NC 27709

COMPANY# 073989 FIFRA ENDANGERED SPECIES TASK FORCE, L.L.C.
 * DATA TYPES * 1350 I STREET, NW
 EU AT EC FW EF OT WASHINGTON, DC 20005
 XX

COMPANY# 074888 RESIDENTIAL EXPOSURE JOINT VENTURE (REJV)
 * DATA TYPES * 900 17TH STREET, NW, SUITE 300
 EU AT EC FW EF OT WASHINGTON, DC 20006
 XX

COMPANY# 075234 AGRICULTURAL HANDLERS EXPOSURE TASK FORCE
 * DATA TYPES * PO BOX 509
 EU AT EC FW EF OT MACON, MO 63552
 XX

COMPANY# 075576 U.S. TRIAZOLE TASK FORCE
 * DATA TYPES * 600 13TH STREET, NW, 12TH FLOOR
 EU AT EC FW EF OT WASHINGTON, DC 20005
 XX XX

COMPANY# 084229 TIDE INTERNATIONAL, USA, INC.
 * DATA TYPES * C/O PYXIS REGULATORY CONSULTING, INC
 EU AT EC FW EF OT 4110 136TH ST. NW
 XX XX GIG HARBOR, WA 98332

CHEMICAL CHEMICAL NAME
 110001 N-(Phenylmethyl)-9-(tetrahydro-2H-pyran-2-yl)-9H-purin-6-amine

COMPANY# 000275 ABBOTT LABORATORIES
 * DATA TYPES * ABBOTT DIAGNOSTICS DIVISION-DEPT. 03A4
 EU AT EC FW EF OT 100 N. ABBOTT PARK ROAD-BLD AP8B
 XX ABBOTT PARK, IL 60064

CHEMICAL CHEMICAL NAME
 110003 Spinosad (Naturally occurring mixture of spinosyn A, pc code 110003 , CAS Reg. No. 131

COMPANY# 000264 BAYER CROPSCIENCE LP
 * DATA TYPES * 2 T.W. ALEXANDER DRIVE
 EU AT EC FW EF OT RESEARCH TRIANGLE PARK, NC 27709
 XX

COMPANY# 000279 FMC CORP. AGRICULTURAL PRODUCTS GROUP
 * DATA TYPES * 1735 MARKET ST
 EU AT EC FW EF OT PHILADELPHIA, PA 19103
 XX XX

COMPANY# 007501 GUSTAFSON LLC
 * DATA TYPES * PO BOX 660065
 EU AT EC FW EF OT DALLAS, TX 75266
 XX XX

COMPANY# 062719 DOW AGROSCIENCES LLC
 * DATA TYPES * 9330 ZIONSVILLE RD 308/2E
 EU AT EC FW EF OT INDIANAPOLIS, IN 46268
 XX XX XX XX

COMPANY# 066607 SPRAY DRIFT TASK FORCE
 * DATA TYPES * 1900 K STREET, NW
 EU AT EC FW EF OT WASHINGTON, DC 20006
 XX

COMPANY# 067702 WALTER G TALAREK
 * DATA TYPES * Agent for: W. NEUDORFF GMBH KG
 EU AT EC FW EF OT 1008 RIVA RIDGE DR
 XX GREAT FALLS, VA 22066

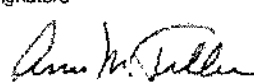
COMPANY# 068467 MYCOGEN SEEDS
 * DATA TYPES * C/O DOW AGROSCIENCES LLC
 EU AT EC FW EF OT 9330 ZIONSVILLE ROAD
 XX XX INDIANAPOLIS, IN 46268

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX


Date July 23, 2008		EPA Reg. No./File Symbol 84229-L		Page / of 5	
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Triadimefon Technical			
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	47327501	Tide International USA, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	47327501	Tide International USA, Inc.	OWN	
830.1620	Description of Production Process	47327501	Tide International USA, Inc.	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	47327501	Tide International USA, Inc.	OWN	
830.1700	Preliminary Analysis	47327502 47327503	Tide International USA, Inc.	OWN	
830.1750	Certified Limits	47327501	Tide International USA, Inc.	OWN	
830.1800	Enforcement Analytical Method	47327501	Tide International USA, Inc.	OWN	
830.6302	Color	47327504	Tide International USA, Inc.	OWN	
830.6303	Physical State	47327504	Tide International USA, Inc.	OWN	
830.6304	Odor	47327504	Tide International USA, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 5	Tide International USA, Inc.	OWN	Waiver ³
830.6314	Oxidation/Reduction; Chemical Incompatibility	47327504	Tide International USA, Inc.	OWN	
830.6315	Flammability	47327505	Tide International USA, Inc.	OWN	Waiver ³
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 23, 2008

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DATA MATRIX

Date July 23, 2008			EPA Reg. No./File Symbol 84229-L		Page 2 of 5
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Triadimefon Technical		
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	47327505	Tide International USA, Inc.	OWN	Waiver ⁴
830.6317	Storage Stability	47327505	Tide International USA, Inc.	OWN	PRN 92-5 ⁵
830.6319	Miscibility				Not required ⁶
830.6320	Corrosion Characteristics	47327505	Tide International USA, Inc.	OWN	PRN 92-5 ⁵
830.6321	Dielectric Breakdown Voltage				Not required ⁷
830.7000	pH	47327504	Tide International USA, Inc.	OWN	
830.7050	UV/Visible Absorption	47327504	Tide International USA, Inc.	OWN	
830.7100	Viscosity	47327505	Tide International USA, Inc.	OWN	Waiver ⁸
830.7200	Melting Point/Melting Range	47327504	Tide International USA, Inc.	OWN	
830.7220	Boiling Point/Boiling Range				Not required ⁹
830.7300	Density/Relative Density/Bulk Density	47327504	Tide International USA, Inc.	OWN	
830.7370	Dissociation Constants in Water	47327505	Tide International USA, Inc.	OWN	Waiver ¹⁰
830.7520	Particle Size, fiber length, and diameter distribution	47327505	Tide International USA, Inc.	OWN	Waiver ¹¹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	47327505	Tide International USA, Inc.	PL	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 23, 2008


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DATA MATRIX

Date July 23, 2008			EPA Reg. No./File Symbol 84229-L		Page 3 of 5
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Triadimefon Technical		
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	47327505 47327504	Tide International USA, Inc.	PL OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	47327505	Tide International USA, Inc.	PL	
870.1100	Acute Oral Toxicity: Rat	47327506	Tide International USA, Inc.	OWN	
870.1200	Acute Dermal Toxicity: Rat	47327507	Tide International USA, Inc.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	47327508	Tide International USA, Inc.	OWN	
870.2400	Primary Eye Irritation: Rabbit	47327509	Tide International USA, Inc.	OWN	
870.2500	Primary Dermal Irritation	47327510	Tide International USA, Inc.	OWN	
870.2600	Dermal Sensitization	47327511	Tide International USA, Inc.	OWN	
Tide International USA, Inc. will make offers-to-pay to the following companies on the March 31, 2008 Data Submitters List for Triadimefon					
Triadimefon Generic Data Requirements					
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer CropScience LP	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer Environmental Science	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 23, 2008


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DATA MATRIX

Date July 23, 2008		EPA Reg. No./File Symbol 84229-L		Page 4 of 5	
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618		Product Triadimefon Technical			
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRI# Number	Submitter	Status	Note
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer Corp.	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		The Andersons Lawn Fertilizer Division	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Woodstream Corp.	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Spray Drift Task Force	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Outdoor Residential Exposure Task Force LLC	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Agricultural Reentry Task Force	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer Advanced	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		FIFRA Endangered Species Task Force LLC	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Agricultural Handlers Exposure Task Force	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Residential Exposure Joint Venture	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date July 23, 2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date July 23, 2008

EPA Reg. No./File Symbol 84229-L

Page 5 of 5


Applicant's/Registrant's Name & Address

Tide International USA, Inc.
21 Hubble
Irvine, CA 92618

Product

Triadimefon Technical

Ingredient Triadimefon (CAS No. 43121-43-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		U.S. Triazole Task Force	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Lanxess Corp.	PAY	
Signature			Name and Title		Date
			Ann M. Tillman, Consultant		July 23, 2008

Endnotes for Data Matrix for Triadimefon Technical

-
- ¹ **830.1650** - These data are not required for the registration of a technical product. See 830.1620 for production process information.
- ² **830.6313** - Tide International USA, Inc. will not be packaging Triadimefon Technical in metal containers, nor is it expected to come into contact with metals or metal ions during its storage. In addition, Triadimefon Technical is not expected to be subjected to temperatures greater than 50°C during its production or storage. Therefore, Tide International USA, Inc. seeks a waiver from the requirement for these data.
- ³ **830.6315** - Tide International USA, Inc. requests a waiver from the requirement for flammability for Triadimefon Technical based on the fact that this technical is a solid and is not expected to be flammable. Please refer to the Confidential Statement of Formula for Triadimefon Technical.
- ⁴ **830.6316** - Tide International USA, Inc. requests a waiver from the requirement of this study. Triadimefon Technical does not have the chemical bonds or functional groups associated with explosive chemicals. Please refer to the Confidential Statement of Formula for additional information on the composition of Triadimefon Technical.
- ⁵ **830.6317 and 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Tide International USA, Inc. agrees to conduct these studies if required and requests that the studies be made a condition of registration.
- ⁶ **830.6319** - These data are required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. Triadimefon Technical is a solid and not an emulsifiable liquid. Therefore, this data requirement is not applicable to Triadimefon Technical.
- ⁷ **830.6321** - These data are required if the end use product is to be used around electrical equipment. Triadimefon Technical is not an end use product and therefore this data requirement is not applicable.
- ⁸ **830.7100** - These data are required when the product is a liquid. Triadimefon Technical is a solid. Therefore, this data requirement is not applicable to Triadimefon Technical.
- ⁹ **830.7220** - Boiling point data are only required for liquids. Triadimefon Technical is a solid. Therefore, this data requirement is not applicable to Triadimefon Technical.
- ¹⁰ **830.7370** - Tide International USA, Inc. is seeking a waiver for the dissociation constant for Triadimefon Technical because the chemical does not contain any functionality that would dissociate. The EPA Reregistration Eligibility Decision document for triadimefon listed this data requirement as not being applicable (Ref.: Reregistration Eligibility Decision for Triadimefon and Tolerance Reassessment for Triadimenol, August 2006, Appendix B-1, page 85).
- ¹¹ Tide International USA, Inc. is seeking a waiver for this data requirement for Triadimefon Technical because the product is not water insoluble nor is it a fibrous material.

DATE OUT: 22/May/ 2008

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP []**
DP BARCODE No.: 349827 EPA File Symbol No.: 84229-L
PRODUCT NAME: Triadimefon Technical
COMPANY: Tide International, USA, Inc.
FOOD USE [] INTEGRATED FORMULATION [X]
PCC: 109901 Decision No. 388811
ACTION CODE: R310

FROM: Hari Mukhoty, DVM, PHD
Product Chemistry Team
Technical Review Branch / RD (7505P)

[Handwritten signature]
8/27/08

TO: Rosemary Kearns / Tony Kish, RM 22
Fungicide Branch / RD (7505P)

INTRODUCTION:

The Registrant has submitted a basic CSF for a new MUP, and has proposed a product specific label (both dated 01/14/2008) to support the registration of the proposed technical product EPA File Symbol 84229-L. The registrant has claimed that the new technical formulation is substantially similar (me-too) in composition and labeling to the registered product EPA Reg. No. 264-736. The cited product was registered on 09/27/1979 and the label was found acceptable on 11/02/2007. The product chemistry data for the cited product has been reviewed and found acceptable on 03/14/1997. The registrant has also submitted the product chemistry data for the proposed MUP under MRIDs 473275-01, -02, -03, -04 and -05.

The TRB has been requested to evaluate the product chemistry data for registration of the proposed MUP and to determine if the proposed product is substantially similar to the cited technical product.

SUMMARY OF FINDINGS:

1. The proposed fungicidal MUP is to be used only for formulation into fungicidal product for non-food uses. The overall mean of the active ingredient from five batch analysis is 98.8396% with a standard deviation of 0.9279.
2. The nominal concentration of the active ingredient in the proposed product is 99.0%. The certified limits of the nominal concentrate is in compliance with 40 CFR§ 158.175 (b) (2). The registrant chose the nominal at 99.0% to allow a little room for the fluctuations of total impurities and variations generating from analytical methods used.
3. The CSF of the basic formulation (dated 01/14/2008) is filled out completely and correctly. The nominal concentration of the active ingredient matches with the label claim. This is in compliance with PR Notice 91-2.

DP BARCODE No.: 349827 EPA File Symbol No.: 84229-L PRODUCT NAME:
Triadimefon Technical

4. The data submitted for Subgroup A corresponding to guidelines 830.1550 (product identity and composition, 830.1600 (materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR § 158.320, 158.325, 158.330, 158.340, and 158.350 respectively [MRID 473275-01].

5. The method proposed corresponding to guideline 830-1700 (preliminary analysis) satisfy the data requirements of 40 CFR§158.345. The concentration of the active ingredient and the impurities were quantified by HPLC/Mass Spectrometry following GC analysis. For GC, a Varian CP-3800 with Autoinjector (117) with an injection volume of 3 µl at 220 C on the volatile sample mode, an FID, and a Phenomenex ZB-5 column (95% methyl polysiloxane) with a length of 30 m, an inner diameter of 0.32 mm, and a film thickness of 1.0 µm. was used. Methods validating accuracy, precision and linearity of results have been provided. Triadimefon may be quantified by GC as stated above for Enforcement Analytical Method [MRID 473275-01 and -02]

6. The proposed MUP is not substantially similar in composition to the cited technical product EPA Reg. No. 264-736. This is because of wide differences in impurities and label texts between these two products. In the proposed product, [REDACTED] major impurity was identified compared to [REDACTED] impurities identified in the registered product. [REDACTED] impurity present in the proposed product is also present in the registered product.

7. The product chemistry data for Group A & B, with the exception of storage stability (830.6317) and corrosion characteristics data (830.6320) are acceptable [473275-01, -02, -03, -04 and -05; see FR Notice, Oct. 26, 2007 40 CFR§ 158.310 (e) & (f)].

8. The registrant stated that the impurities in the proposed MUP are of no toxicological concern based on the FAO specification [MRID 473275-01 on page 16]

CONCLUSIONS:

1. TRB has reviewed the proposed basic CSF (dated 01/14/2008) for technical formulation and has found it to be acceptable.

2. The proposed basic MUP is not substantially similar to the cited product because of differences in the label text and impurity profile.

3. The product chemistry data submitted for the guidelines 830 Series Group A and Group B, with the exception of storage stability (830.6317) and corrosion characteristics (830.6320), are acceptable.

4. The registrant shall generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is recommended that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in the electronic format and as well as a hard copy.

5. The registrant certifies that impurities present in the proposed MUP are of no toxicological significance.

DP BARCODE No.: 349827 EPA File Symbol No.: 84229-L PRODUCT NAME:
Triadimefon Technical

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity	A	47327501
830.1600. Beginning Materials	A	47327501
830.1620. Production Process	A	47327501
830.1670. Discussion of Impurities	A	47327501
830.1700. Preliminary Analysis	A	47327502
830.1750. Certified Limits (Basic CSF dated 01/14/2008)	A	47327501
830.1800. Enforcement Analytical Method	A	47327501

DP BARCODE No.: 349827 EPA File Symbol No.: 84229-L PRODUCT NAME:
Triadimefon Technical

Group B	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
830.6302. Color	A	White to off- White	47327504
830.6303. Physical State	A	Powder	47327504
830.6304. Odor	A	Faint decaying to foul or /sulfurous	47327504
830.6313. Stability to normal and elevated temp, metals and metal ions	N/A		47327505
830-6314. Oxidation/Reduction action ~ Chemical incompatibility	A	Compatible with all reagents	47327504
830.6315. Flammability	N/A	Not flammable	47327505
830.6316. Explodability	N/A	No chemical bonds or functional groups of explosivity	47327505
830.6317. Storage stability	G	Required	47327505
830.6319. Miscibility	N/A	Not emulsifiable & diluted with petroleum	47327505
830.6320. Corrosion Characteristics	G	Required	47327505
830.7200. Boiling point	N/A	Not required	

18

830.7050. UV/visible light absorption	A	Maxima: at 221-276 nm for neutral, at 221-275 nm for acidic, & at 222-275 nm for basic sol at 0.0011, 0.0007 dilutions respectively.	47327504
830.7370. Dissociation Constant (cited)	A	Not required per RED	47327505
830.7550. Partition Coefficient (cited)	A	$K_{ow} \log P = 3.11$	47327405
830.7950. Vapor Pressure (cited)	A	0.02 mPa at 20°C	47327405
830.7840. Solubility (Cited for water)	A	64 mg/L in water at 20°C. Solubility of Triadimefon in Hexane is 0.54 g/100 ml, in Methanol is 43.38 g/100 ml and in 1-octanol is 8.77 g/100 ml.	47327405, - 04
830.7000. pH	A	6.41 (1% aq) at 25°C	47327404
830.7300. Density/True Density	A	1.32 g/mL	47327504 & CSF (dated 1/14/08)

Explanations: A = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

EPA Registration Number 84229-5

Page _____ is not included in this copy.

Pages 20 through 37 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

☒ Description of the product manufacturing process.

☒ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-client communication.

_____ Claimed confidential by submitter upon submission to the Agency.

_____ Personal privacy Information

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

11/JUN/2008

MEMORANDUM

Subject: Name of Pesticide Product: Triadimefon Technical
EPA File Symbol: 84229-L
DP Barcode: D349845
Decision No.: 388811
Action Code: R310
PC Code: 109901 (triadimefon)

From: Eugenia McAndrew, Biologist *E. McAndrew*
Technical Review Branch *RM Kearns*
Registration Division (7505P) *6/11/08*

To: Rosemary Kearns, RM Team 22
Fungicide Branch
Registration Division (7505P)

Applicant: Tide International USA, Inc.
21 Hubble
Irvine, CA 92618

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Triadimefon.	99.0
<u>Inert Ingredient(s):</u>	<u>1.0</u>
	Total: 100.0%

ACTION REQUESTED: The Risk Manager requests review of acute toxicity data for 84229-L.

BACKGROUND: Tide International USA, Inc has submitted a six pack of acute toxicity studies to support the proposed product, Triadimefon Technical, EPA File Symbol 84229-L. The studies were conducted at Stillmeadow, Inc. with assigned MRID numbers 473275-06 to -11. A CSF dated January 14, 2008 for a basic formulation is included in the submission. An Agency contractor, Oak Ridge National Laboratory, conducted the primary review of the studies. TRB performed the secondary review and made changes as necessary.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable.

The acute toxicity profile for Triadimefon Technical, EPA File Symbol 84229-L, is as follows:

Acute oral toxicity	III	Acceptable	MRID 47327506
Acute dermal toxicity	IV	Acceptable	MRID 47327507
Acute inhalation toxicity	IV	Acceptable	MRID 47327508
Primary eye irritation	IV	Acceptable	MRID 47327509
Primary skin irritation	IV	Acceptable	MRID 47327510
Dermal sensitization	Negative	Acceptable	MRID 47327511

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for the proposed product as obtained from the Label Review System:

PRODUCT ID #: 084229-00005

PRODUCT NAME: Triadimefon Technical

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA EVALUATION RECORD

TRIADIMEFON

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OPPTS 870.1100; OECD 425]
ACUTE DERMAL TOXICITY - RAT [OPPTS 870.1200; OECD 402]
ACUTE INHALATION TOXICITY - RAT [OPPTS 870.1300; OECD 403]
ACUTE EYE IRRITATION - RABBIT [OPPTS 870.2400; OECD 405]
ACUTE DERMAL IRRITATION - RABBIT [OPPTS 870.2500; OECD 404]
DERMAL SENSITIZATION - GUINEA PIG [OPPTS 870.2600; OECD 406]
MRID: 47327506, 47327507, 47327508, 47327509, 47327510, and 47327511

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by

Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 1-19

Primary Reviewer:
Donna L. Fefee, D.V.M.

Signature: Robert H. Ross
Date: APR 30 2008

Secondary Reviewers:
Dana F. Glass, D.V.M.

Signature: Dana F. Glass
Date: APR 30 2008

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: APR 30 2008

Quality Assurance:
Kimberly G. Slusher, M.S.

Signature: Kimberly G. Slusher
Date: APR 30 2008

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Reviewer: ORNL
Risk Manager (EPA): 22

Date: April 26, 2008

STUDY TYPE: Acute Oral Toxicity – Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: Triadamefon Technical; 98.95% a.i.; Batch No. 20060913; white powder; stored at room temperature

CITATION: Kuhn, J. (2007) Acute oral toxicity study (UDP) in rats. Study Number 10528-06. Unpublished study prepared by STILLMEADOW, Inc., Sugar Land, Texas. March 30, 2007. MRID 47327506.

SPONSOR: Zhejiang Tide Cropscience Co., Ltd., Irvine, California.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 47327506), 12 fasted female Sprague-Dawley albino rats were given single oral gavage doses of Triadamefon Technical (98.95% a.i.; Batch No. 20060913) in deionized water (40% or 50% w/v concentrations) at dose levels of 175 (1 animal), 550 (1 animal), 1750 (3 animals), or 5000 (7 animals) mg/kg bw and then observed for 14 days. The animals weighed 172-201 g and were supplied by Texas Animal Specialties, Humble, Texas. Dosing was conducted as an initial limit test with three animals at 5000 mg/kg bw (100% mortality) and then according to AOT425statpgm.

The animals dosed at 5000 mg/kg bw in the limit test died on days 1 or 3, and the four animals dosed at 5000 mg/kg bw in the up-and-down procedure died during days 2-6. Two/three animals dosed at 1750 mg/kg bw died on days 5 or 7. Abnormal clinical signs in the animals that died included tremors, ataxia, loss of righting reflex, sensitivity to sound or touch, decreased activity, alopecia or swelling around the eyes, diarrhea, polyuria, lateral recumbency, and nasal discharge. The surviving 1750 mg/kg animal exhibited hyperactivity (days 0-1) followed by emaciation, piloerection, sensitivity to touch, hunched posture, and biting at it's tail and cage on day 3, with recovery by day 4. The animals dosed at 175 and 550 mg/kg bw appeared normal for the duration of the study, and all of the surviving animals gained weight during both weeks of the study. Abnormal gross necropsy findings were noted in the animals that died and included the following: emaciation, red discoloration of the lungs, grey or dark red and brown discoloration of the liver, discolored and/or liquid gastrointestinal contents or empty gastrointestinal tract, and/or matted, wet, stained, or crusted fur.

LD₅₀ Females = 1750 mg/kg bw (95% PL Confidence interval 316.4 to 2720 mg/kg bw)

Based on the acute oral LD₅₀, Triadamefon Technical is in EPA Toxicity Category III.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Saturday, April 26, 2008, 11:54:24 PM
Data file name: work.dat
Last modified: 4/26/2008 11:54:20 PM

Test/Substance: Triadamefon Technical
Test type: Main Test
Limit dose (mg/kg): 5000
Assumed LD50 (mg/kg): Default
Assumed sigma (mg/kg): 0.5

Recommended dose progression: 5000, 1750, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	111	175	O	O
2	112	550	O	O
3	113	1750	O	O
4	114	5000	O	X
5	115	5000	X	X
6	116	1750	O	X
7	117	5000	X	X
8	118	1750	O	X
9	119	5000	X	X

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.
Stopping criteria met: 5 reversals in 6 tests.

SUMMARY OF LONG-TERM RESULTS in MAIN TEST:

Dose	O	X	Total
175	1	0	1
550	1	0	1
1750	1	2	3
5000	0	4	4
All Doses	3	6	9

Statistical Estimate based on long term outcomes:

Estimated LD₅₀ = 1750 (The one dose with partial response).

95% PL Confidence interval is 316.4 to 2720.

- A. **Mortality**: The animals dosed at 5000 mg/kg bw in the limit test died on day 1 (two animals) or day 3 (1 animal). The four animals dosed at 5000 mg/kg bw in the up-and-down procedure died during days 2-6. Two/three animals dosed at 1750 mg/kg bw died, one each on days 5 and 7.
- B. **Clinical observations**: Clinical signs in the animals that died included tremors, ataxia, loss of righting reflex, sensitivity to sound or touch, decreased activity, alopecia or swelling around the eyes, diarrhea, polyuria, lateral recumbency, and nasal discharge. Clinical signs in the surviving 1750 mg/kg animal included hyperactivity (days 0-1) followed by emaciation, piloerection, sensitivity to touch, hunched posture, and biting at it's tail and cage on day 3, with recovery by day 4. The animals dosed at 175 and 550 mg/kg bw appeared normal for the duration of the study, and all of the surviving animals gained weight during both weeks of the study.
- C. **Gross necropsy**: Findings from the surviving 1750 mg/kg animal were not recorded, and there were no abnormal findings in the other surviving animals. Abnormal findings in the animals that died included emaciation, red discoloration of the lungs, grey or dark red and brown discoloration of the liver, discolored and/or liquid gastrointestinal contents or empty gastrointestinal tract, and/or matted, wet, stained, or crusted fur.
- D. **Reviewer's conclusions**: The acute oral LD₅₀ in females is 1750 mg/kg bw (95% PL Confidence interval 316.4 to 2720 mg/kg bw). This places the test material in EPA Toxicity Category III.
- E. **Deviations**: Gross necropsy results were not recorded for Animal # 113 which was dosed at 1750 mg/kg. This deviation did not affect the outcome of the study.

Reviewer: ORNL
Risk Manager (EPA): 22

Date: April 27, 2008

STUDY TYPE: Acute Dermal Toxicity – Rabbit; OPPTS 870.1200; OECD 402

TEST MATERIAL: Triadamefon Technical; 98.95% a.i.; Batch No. 20060913; white powder; stored at room temperature

CITATION: Kuhn, J. (2007) Acute dermal toxicity study in rabbits. Study Number 10529-06. Unpublished study prepared by STILLMEADOW, Inc., Sugar Land, Texas. February 22, 2007. MRID 47327507.

SPONSOR: Zhejiang Tide Cropsience Co., Ltd., Irvine, California.

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 47327507), groups of five male and five female New Zealand white rabbits were dermally exposed to Triadamefon Technical (98.95% a.i.; Batch No. 20060913) moistened with deionized water at a dose of 5050 mg/kg bw for 24 hours. The doses were applied to clipped application sites on the dorsal trunk (~10% of the body surface area), covered by an 8 inch by 4 inch, 4-ply surgical gauze patch secured with non-irritating adhesive tape, and further protected by wrapping the trunk of the animal with an orthopedic stockinette that was held in place with non-irritating adhesive tape. The animals were then observed for 14 days, including evaluation of the dose sites for dermal irritation on days 1, 4, 7, 11, and 14. The animals were 2-3 months old (males: 2.60-2.85 kg; females: 3.35-2.95 kg) and supplied by Nichols Rabbitry Inc., Lumberton, Texas.

There were no deaths, and abnormal clinical signs were limited to very slight erythema on the application sites of two females on day 1 and alopecia on the forepaws of two males on day 7 through day 13 or 14. Two males and one female lost weight during the first week but gained sufficient weight during the second week so that their initial body weights were exceeded. The remaining animals gained weight during both weeks of the study. There were no abnormal gross necropsy findings.

LD₅₀ Males > 5050 mg/kg bw
LD₅₀ Females > 5050 mg/kg bw
LD₅₀ Combined > 5050 mg/kg bw

Based on the acute dermal LD₅₀, Triadamefon Technical is in EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute dermal study (OPPTS 870.1200; OECD 402) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5050	0/5	0/5	0/10

A. **Mortality:** There were no deaths.

B. **Clinical observations:** Abnormal clinical signs were limited to very slight erythema on the application sites of two females on day 1 and alopecia on the forepaws of two males on day 7 through day 13 or 14. Two males and one female lost weight during the first week but gained sufficient weight during the second week so that their initial body weights were exceeded. The remaining animals gained weight during both weeks of the study.

C. **Gross necropsy:** There were no abnormal findings.

D. **Reviewer's conclusions:** In agreement with the study author, the acute dermal LD₅₀ for males, females, and the combined sexes is greater than 5050 mg/kg bw. This places the test material in EPA Toxicity Category IV.

Reviewer: ORNL
Risk Manager (EPA): 22

Date: April 27, 1008

STUDY TYPE: Acute Inhalation Toxicity – Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: Triadamefon Technical; 98.95% a.i.; Batch No. 20060913; white powder; stored at room temperature

CITATION: Crutchfield, V. (2007) Acute inhalation toxicity study in rats. Study Number 10530-06. Unpublished study prepared by STILLMEADOW, Inc., Sugar Land, Texas. March 5, 2007. MRID 47327508.

SPONSOR: Zhejiang Tide Cropscience Co., Ltd., Irvine, California.

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47327508), groups of five male and five female Sprague-Dawley rats were exposed by nose-only inhalation to finely ground, undiluted Triadamefon Technical (98.95% a.i.; Batch No. 20060913) as an aerosol at a mean gravimetric concentration of 2.27 mg/L for 4 hours. The animals were observed for 14 days. The MMAD was 3.1 μ m and the GSD was 5.95. The animals were approximately 8-9 weeks old (males: 270-309 g; females: 183-202 g) and supplied by Texas Animal Specialties, Humble, Texas.

There were no deaths or abnormal gross necropsy findings. All of the animals exhibited piloerection and decreased activity beginning on day 0, half an hour after exposure, and continuing through day 5. All of the animals gained weight during both weeks of the study; however, two females gained only 1-2 g during the first week.

LC₅₀ Males > 2.27 mg/L
LC₅₀ Females > 2.27 mg/L
LC₅₀ Combined > 2.27 mg/L

Based on the 4-hour inhalation exposure LC₅₀, Triadamefon Technical is classified as EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD (μm)	GSD	Mortality/Number Tested		
				Males	Females	Combined
12.9	1.98-2.41	3.0-3.2	5.9-6.0	0/5	0/5	0/10

Test atmosphere / Chamber description: The test material was aspirated from a motorized revolving disc delivery system coupled to a Gem T Trost Air Mill, and the resultant aerosol was sprayed directly into the 500-liter, nose-only, stainless-steel inhalation chamber. Chamber airflow was maintained via a calibrated orifice plate.

Gravimetric Conc. (mg/L):	1.98-2.41
Chamber Volume (L):	500
Total Airflow (L/min):	181
Temperature ($^{\circ}\text{C}$)	20.1-20.6
Relative Humidity (%)	34.8-37.1
Time to equilibrium (minutes):	13

Test atmosphere concentration: Gravimetric samples were collected from the breathing zone of the animals at 30-minute intervals during exposure (8 samples in all). The test atmosphere was drawn through pre-weighed filters at a rate of 1.87 L/min for one minute, and the mass collected was divided by the total volume of air sampled.

Particle size determination: Samples were collected twice during exposure by drawing air (at 7.3 L/min for 20 seconds) through an 8-Stage cascade impactor. The mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD) were determined using probit analysis software.

A. **Mortality:** There were no deaths.

B. **Clinical observations:** All of the animals exhibited piloerection and decreased activity beginning on day 0, half an hour after exposure, and continuing through day 5. All of the animals gained weight during both weeks of the study; however, two females gained only 1-2 g during the first week.

C. **Gross necropsy:** There were no abnormal findings.

D. **Reviewer's conclusions:** The 4-hour inhalation exposure LC_{50} for males, females, and the combined sexes is greater than 2.27 mg/L. This places the test material in EPA Toxicity Category IV.

Reviewer: ORNL
Risk Manager (EPA): 22

Date: April 27, 2008

STUDY TYPE: Primary Eye Irritation – Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL: Triadamefon Technical; 98.95% a.i.; Batch No. 20060913; white powder; stored at room temperature

CITATION: Kuhn, J. (2007) Acute eye irritation study in rabbits. Study Number 10531-06. Unpublished study prepared by STILLMEADOW, Inc., Sugar Land, Texas. February 13, 2007. MRID 47327509.

SPONSOR: Zhejiang Tide Cropscience Co., Ltd., Irvine, California.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 47327509), 0.1 mL (68.5 mg) of undiluted Triadamefon Technical (98.95% a.i.; Batch No. 20060913) was instilled into the conjunctival sac of the right eye of 2 male and 1 female New Zealand white rabbits, and the upper and lower lids were held shut for approximately one second. Eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation, and the irritation scores were classified according to the system of Kay and Calandra. Treated eyes were washed with room temperature deionized water for 1 minute upon completion of the 24-hour observation, and the untreated left eye of each animal served as a control. The animals were supplied by Nichols Rabbitry Inc., Lumberton, Texas (males: 2.93-3.10 kg; female: 3.05 kg).

One hour after treatment, all treated eyes showed a trace of the test material, and one had grade 1 iritis, grade 1 corneal opacity involving greater than 75% of the cornea, and grade 2 conjunctival redness. All treated eyes were normal at 24 hours, and there was also no uptake of fluorescein stain at this time point. The maximum mean total score (MMTS) was 9.7, recorded 1 hour after test material instillation.

In this study, the formulation is minimally irritating. Triadamefon Technical is classified as EPA Toxicity Category IV for primary eye irritation.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Observations	Number "positive"/Number treated			
	Hours			
	1	24	48	72
Corneal Opacity	1/3	0/3	0/3	0/3
Iritis	1/3	0/3	0/3	0/3
Conjunctivae:				
Redness*	1/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3
Discharge**	0/3	0/3	0/3	0/3

* Score of 2 or more required to be considered "positive"

** Discharge does not indicate a positive effect according to the grading scale

- A. **Observations:** One hour after treatment, all treated eyes showed a trace of the test material, and one had grade 1 iritis, grade 1 corneal opacity involving greater than 75% of the cornea, and grade 2 conjunctival redness. All treated eyes were normal at 24 hours, and there was also no uptake of fluorescein stain at this time point.
- B. **Results:** The maximum mean total score (MMTS) was 9.7, recorded 1 hour after test material instillation.
- C. **Reviewer's conclusions:** The test material is minimally irritating to the eye and is classified as EPA Toxicity Category IV.

Reviewer: ORNL
Risk Manager (EPA): 22

Date: April 26, 2008

STUDY TYPE: Primary Dermal Irritation – Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: Triadamefon Technical; 98.95% a.i.; Batch No. 20060913; white powder; stored at room temperature

CITATION: Kuhn, J. (2007) Acute dermal irritation study in rabbits. Study Number 10532-06. Unpublished study prepared by STILLMEADOW, Inc., Sugar Land, Texas. February 6, 2007. MRID 47327510.

SPONSOR: Zhejiang Tide Cropsience Co., Ltd., Irvine, California.

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 47327510), two male and one female New Zealand White rabbits were dermally exposed for 4 hours to 500 mg of Triadamefon Technical (98.95% a.i.; Batch No. 20060913) moistened with 0.1 mL of deionized water. The doses were applied to intact, clipped application sites on the dorsal trunk, covered by a 2.5 cm by 2.5 cm, 4-ply gauze patch, which was secured to the skin with non-irritating adhesive tape and protected by wrapping the trunk of the animal with an orthopedic stockinette that was held in place with non-irritating adhesive tape. The application sites were observed and scored at 1, 24, 48, and 72 hours after patch removal. The animals were approximately 3 months old (males: 3.10-3.28 kg; female: 3.08 kg) and supplied by Nichols Rabbitry Inc., Lumberton, Texas.

No erythema, edema, or other signs of dermal irritation were noted on any animal at any time during the study.

In this study, the formulation is non-irritating. Triadamefon Technical is classified as EPA Toxicity Category IV for primary dermal irritation. The Primary Irritation Index (PII) = 0.0.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Animal Number	Sex	Hours			
		1	24	48	72
1086	Male	0/0 ^a	0/0	0/0	0/0
1088	Male	0/0	0/0	0/0	0/0
1093	Female	0/0	0/0	0/0	0/0
Severity of Irritation: Mean Score		0.0/0.0	0.0/0.0	0.0/0.0	0.0/0.0

^a Erythema/Edema

- A. **Observations:** No erythema, edema, or other signs of dermal irritation were noted on any animal at any time during the study.
- B. **Results:** The Primary Irritation Index (PII) was 0.0.
- C. **Reviewer's conclusions:** In agreement with the study author, the test material was non-irritating and is classified as EPA Toxicity Category IV for skin effects.

Reviewer: ORNL
Risk Manager (EPA): 22

Date: April 26, 2008

STUDY TYPE: Dermal Sensitization – Guinea Pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: Triadimefon Technical; 98.95% a.i.; Batch No. 20060913; white powder; stored at room temperature

CITATION: Kuhn, J. (2007) Skin sensitization study in guinea pigs. Study Number 10533-06. Unpublished study prepared by STILLMEADOW, Inc., Sugar Land, Texas. March 15, 2007. MRID 47327511.

SPONSOR: Zhejiang Tide Cropsience Co., Ltd., Irvine, California.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47327511), 15 male and 15 female Hartley-Albino guinea pigs were tested using the Buehler method with 400 mg of Triadimefon Technical (98.95% a.i.; Batch No. 20060913) moistened with 0.4 mL of deionized water. The animals were approximately 4 weeks old (males: 319-378 g; females: 325-378 g) and supplied by Charles River Laboratories, Wilmington, Massachusetts.

For each of three successive weekly inductions, 400 mg of the test material moistened with 0.4 mL of deionized water was applied to twenty test animals for a six hour exposure period. After a two week rest period, the 20 test animals and 10 naïve control animals were challenged with 400 mg of the test material moistened with 0.4 mL of deionized water. Following challenge, no erythema was seen at any dose site.

Based on the results of this study, Triadimefon Technical is *not* a dermal sensitizer.

This study is classified as acceptable. It does satisfy the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

PROCEDURE:

- A. **Induction**: The dorsal trunk of each animal was clipped one day prior to each treatment. For each of three successive weekly inductions, 400 mg of the test material moistened with 0.4 mL of deionized water was applied beneath a 4-ply, 2.5 cm by 2.5 cm surgical gauze patch placed laterally from the midline on the left front quadrant of the dorsal trunk and secured with nonirritating adhesive tape. The patch was then covered with a securely taped strip of clear polyethylene film, and each animal was placed in a restrainer for the duration of the 6-hour exposure. Reactions were scored at 24 and 48 hours after the first induction and at 24 hours (only) after the second and third induction.
- B. **Challenge**: Twenty-eight days after the first induction, the animals were challenged with 400 mg of the test material moistened with 0.4 mL of deionized water applied to (previously clipped) naive sites lateral to the midline on the right rear quadrant of the dorsal trunk for 6 hours using the same procedure. Reactions were scored 24 and 48 hours post application.
- C. **Naïve controls**: At challenge a separate "naïve" group of 10 previously untreated animals (5 male and 5 female) was also treated with 400 mg of the test material moistened with 0.4 mL of deionized water using the same procedure. Reactions were scored 24 and 48 hours post application.

RESULTS and DISCUSSION:

- A. **Reactions and durations**: No reactions were seen at any dose site, following induction or challenge.
- B. **Positive control**: The results of a positive control study using 1-chloro-2,4-dinitrobenzene (DNCB) were included in the study report. The study was conducted within six months of the submitted study, and the results were appropriate.
- C. **Reviewer's conclusion**: In agreement with the study author, the test material is not a dermal sensitizer.

1. **DP BARCODE:** D349845
2. **PC CODE:** 109901
3. **CURRENT DATE:** April 27, 2008
4. **TEST MATERIAL:** Triadimefon (Triadamefon Technical); 98.95% a.i.; Batch No. 20060913; white powder; stored at room temperature

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat STILLMEADOW, Inc. Study #10528-06/March 30, 2007	47327506	LD ₅₀ Females = 1750 mg/kg bw	III	A
Acute dermal toxicity/rabbit STILLMEADOW, Inc. Study #10529-06/February 22, 2007	47327507	LD ₅₀ > 5050 mg/kg bw Males, females combined	IV	A
Acute inhalation toxicity/rat STILLMEADOW, Inc. Study #10530-06/March 5, 2007	47327508	LC ₅₀ Males > 2.27 mg/L LC ₅₀ Females > 2.27 mg/L LC ₅₀ Combined > 2.27 mg/L	IV	A
Primary eye irritation/rabbit STILLMEADOW, Inc. Study #10531-06/February 13, 2007	47327509	Minimally irritating	IV	A
Primary dermal irritation/ rabbit STILLMEADOW, Inc. Study #10532-06/February 6, 2007	47327510	Non irritating PII = 0.0	IV	A
Dermal sensitization/guinea pig STILLMEADOW, Inc. Study #10533-06/March 15, 2007	47327511	Not a sensitizer	--	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived

54

REQUEST FOR WORK TO BE DONE BY THE CONTRACTOR

- (1) Date: 03/24/08
- (2) Name of Contractor: ORNL
- (3) Task #: 1 - 19
- (4) EPA Requesting Reviewer Name: Debbie McCall Tele.#: 703-605-0717
- (5) Chemical Name: Triadimefon
- (6) CBI: NO X FIFRA: YES X NO PRIA: YES X NO
- (7) Description for Each Study: (Identify the type of study to be evaluated, provide the information requested and describe the type of work to be performed if different from the following statement - be specific).

P.Code 109901 Chem: ; Date required by: (opt) Apr. 29, 2008

DP barcode: 349845; Submission: S ; TXR #¹:

Registration: x Reregistration: Special Review:

Evaluate and prepare a DER for the following studies:

<u>STUDY description</u>	<u>MRID #</u>	<u># Hrs.</u>	<u>DER WAM/Reviewer</u>
Acute Oral Toxicity	473275-06		
Acute Dermal Toxicity	473275-07		
Acute Inhalation Toxicity	473275-08		
Primary Eye Irritation	473275-09		
Primary Skin Irritation	473275-10		
Dermal Sensitization	473275-11		
<u>Total Number of Review Hours Assigned</u>	24		

¹Lead Toxicologist for the package should request a TXR # (as per IHAD SOP) from SIMB; each DER should have the TXR # underneath the HED signature block.

Approval:

D. McCall
Requesting Branch Chief/WAM

3-24-08 ^{LM}
Date

Joanne L. Miller
Project Officer

3-24-08
Date

Return by Date: 04/29/2008

55

PRIA fee has been pre-paid.

Copy of check/pay.gov
receipt enclosed.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 24, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-388811
EPA File Symbol or Registration Number: 84229-L
Product Name: TRIADIMEFON TECHNICAL
EPA Receipt Date: 22-Jan-2008
EPA Company Number: 84229
Company Name: TIDE INTERNATIONAL, USA, INC.

JANELLE KAY
TIDE INTERNATIONAL, USA, INC.
C/O PYXIS REGULATORY CONSULTING, INC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in cursive script, reading "Teresa Owens", is written over the printed name.

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{823115W~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies? ☐ Fee Waiver?
☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 22

Receipt No.

S-

823115

EPA File Symbol/Reg. No.

84229L

Pin-Punch Date:

1/22/2008

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R310

Amount Due: \$ 4,360

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

Uncleared Inert in Product

Reviewer: 

Date: 1/24/08

Remarks: Technical + Impurities only. No inerts for review.

R. Debesai
1/23/08

58

FEE FOR SERVICE

S: 823115

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 84229 TIDE INTERNATIONAL, USA, INC.

V

Risk Manager: Registration Division, Risk Management Team 22

Product #: 84229-L

Product Name: TRIADIMEFON TECHNICAL

Override#:

Me Too Section 3: 264-736

Me Too Product Name: BAYLETON TECHNICAL FUNGICIDE

Application Date: 15-Jan-2008

OPP Rec'd Date: 22-Jan-2008

Front End Date: 23-Jan-2008

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for registration for a new technical product

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

60

Online Payment

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 24UGL9V8

Agency Tracking ID: 74038552553

Transaction Date and Time: 01/21/2008 14:21 EST

Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: Der I Wang 2007A, Via Billing Address: Mariposa West Billing Address 2: City: Laguna Woods State / Province: CA Zip / Postal Code: 92637 Country: USA	American Card Type: Express Card Number: *****1006 Expiration Date: 5 / 2010 Decision Number: Registration Number:	Payment Amount: \$4,360.00 Transaction Date 01/21/2008 and Time: 14:21 EST

Do you want to a new plastic card?

661



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

115

Application for Pesticide - Section I

1. Company/Product Number 84229- L	2. EPA Product Manager T. Kish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product Name Tide International USA, Inc./Triadimefon Technical	PM# 22	
5. Name and Address of Applicant (Include ZIP Code) Tide International USA, Inc. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 264-736 (formerly 3125-319) Product Name Bayleton Technical Fungicide	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R310 (46: New manufacturing use product) because it is an application for registration (using the cite-all method of support) for a new technical product substantially similar to a currently registered product. The fee which has been paid is \$4360 and the decision timeline is 6 months.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
* Certification must be submitted				<input checked="" type="checkbox"/> Other (Specify) lined HDPE drum	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 50 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		7. Date Application Received (Stamped) 62
2. Signature 	3. Title Agent	
4. Typed Name Ann Tillman	5. Date 1/15/08	

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

Jan. 15, 2008

OVERNIGHT DELIVERY

Tony Kish (PM 22)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Mr. Kish,

RE: Tide International USA, Inc.
Triadimefon Technical (EPA Reg. No. 84229-)
Application for New Pesticide Registration

On behalf of Tide International USA, Inc., we are submitting an application for registration of Triadimefon Technical. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Five (5) Copies of the Proposed Labeling
4. Certification with Respect to Citation of Data (EPA Form 8570-34)
5. Agency Internal Use Copy of the Data Matrix
6. Public File Copy of the Data Matrix
7. Copy of PRIA payment
8. Letter of Authorization
9. Product Specific Data (3 copies of each report):

Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Tillman, A.M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method for Triadimefon Technical. <i>Contains Confidential Business Information</i>
Volume 2	830.1700	Kaminsky, M. Triadimefon Technical. Preliminary Analysis. <i>Contains Confidential Business Information</i>
Volume 3	830.1700	Kaminsky, M. Triadimefon Technical: Validated Analytical Method to Analyze an Impurity of Toxicological Concern in a Technical Grade Material. <i>Contains Confidential Business Information</i>

63



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

 401 M Street, S.W.
 WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Tide International USA, Inc. c/o Pyxis Regulatory Consulting 4701 1st St NW City Harbor, WA 98112	EPA Registration Number/File Symbol 84229-
Active Ingredient(s) and/or representative test compound(s) Triadimefon	Date Jan. 15, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non-food crop; Greenhouse non-food	Product Name Triadimefon Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION II: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, the form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to use that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Jan 15, 2008

Typed or Printed Name and Title

Ann M. Tillman, Agent

64

Completion of 21-Day Content Screen

PM- 22

EPA Reg. # (File Symbol) _____

Decision # **D** 388811

Data package delivered to
you on 1/29/08.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you,



Registration Division's 21-Day Content Team

Reg Number: 84229-L Reg Type: Product Registration - Section 3 Status: Under Review (23-Jan-2008)
Name: TRIADIMEFON TECHNICAL <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
---	-----------------	----------------	--------------	-------------

...Decisions...

- Data Requirements
- D: Pending; 388811; 84229-L; R310; NEW PRODU
- S: 823115; 7/22/2008; New Registration; 842

S: 823115 Reg #: 84229-L

Submission Type: New Registration

Resubmission?: ☐ Yes ☒ No

Decision #: 388811; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDES)

Submitter Company: TIDE INTERNATIONAL, USA, INC.

Application Date: 15-Jan-2008

OPP Received Date: 22-Jan-2008

Date Sent to Risk manager: 24-Jan-2008

Studies Included?: ☐ Yes ☒ No

Fast Track?: ☐ Yes ☒ No

Form A Signed?: ☐ Yes ☐ No ☒ None

Date:

Form B Signed?: ☐ Yes ☐ No ☒ None

Date:

Reviewer: Kearns, Rosemary

Received DT:

Editable Due DT:

Submission Due DT: 10-Aug-2008

Response: D, 22-Jan-2008

Priority Weight:

Priority Points:

Comments: CSF /labeling/Cert w/resp data/ data matrix/ Ltr of Auth /
product chem & acute tox (Mrid # 473275-01 to -11)

FEB 1 2008

666

Tony:

you may check this out. I had to
check because it was cited to support
Reg. of 84229-L.

① CSF dated 10/16/1996. U.S. manufacturer
Nominal 93.06%.

② CSF dated 10/17/1997- manufac. in
China Nominal 97.7%.

Prod. Chem. review. accepted
on 3/14/97. O.K.

③ Then later on 12/15/1997, Sam
Rejected to make nominal =
label claim without 5 batch.

I cannot find the review / the
MRID to make sure what
is the overall mean of 5-batch.

④ Mel is searching his docs.

Thank

HARL

All docs
attached

Bayleton® Technical Fungicide

For use in the manufacture of fungicides.

ACTIVE INGREDIENT:

1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone..... 97.7% ✓

INERT INGREDIENTS:

2.3%

100.0%

EPA Reg. No. 264-736

EPA Est. No. 3125-MO-1

STOP - Read the label before use
Keep out of reach of children
WARNING

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note To Physician: No specific antidote. Treat symptomatically. The compound does not cause any definite symptoms that would be diagnostic. Poisoning is accompanied by hyperactivity followed by sedation.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

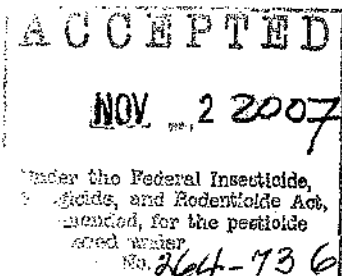
WARNING

May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic skin reactions in some susceptible individuals. Avoid breathing dust and contact with skin, eyes or clothing. Wash thoroughly with soap and warm water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash separately with soap and hot water before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Label Accepted
on 2006 11/2/2007



Reg. 09/27/1979

Transferred to
Bayer on 12/20/2000
Corp EPA 3125-319

68

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a fungicide, for

(1) the following uses:

- a. Terrestrial Food Crop: pineapple.
- b. Terrestrial Non-Food Crop: pine seed, Christmas trees, turf and ornamentals
- c. Greenhouse Non-Food Crop: ornamentals
- d. Residential Outdoor: ornamentals.

(2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and.

(3) uses for experimental purposes that are in compliance with USEPA requirements.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ALL LIABILITY BASED ON BREACH OF WARRANTY, NEGLIGENCE, STRICT TORT LIABILITY, OR ANY OTHER THEORY OF LIABILITY FOR CROP DAMAGE OR FAILED EFFICACY RESULTING FROM THE USE OF THIS BAYER CROPSCIENCE PRODUCT AS AN INGREDIENT IN ANY FORMULATION WITH A USE NOT SPECIFICALLY LISTED ON THIS LABEL.

Detailed information on chemical and physical properties and other formulating recommendations for Bayleton are available upon request from Bayer CropScience. Obtain and read this information before undertaking the formulation of Bayleton in order to avoid formulation hazards and insure a satisfactory finished product.

Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency. For specific information on federally registered uses, contact Bayer CropScience. Any variance from the federally registered labeling for products containing Bayleton will have to be supported by data provided by the formulator.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

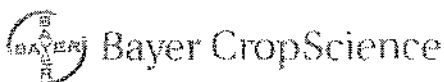
Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer CropScience Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer CropScience Emergency Response Telephone No. is 1-800-334-7577.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not use container in connection with food, feed, or drinking water. Completely empty container into the processing equipment. Then dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

NET CONTENTS:

PRODUCED FOR



2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

Bayleton Technical (PENDING) 07/11/07

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

2631
Cell # (919) 270-0532

Melvin K. Tolliver
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

NOV 02 2007

Subject: Your Submission Dated July 13, 2007
Revised Labeling Per Triadimenfon June 20, 2007 Cancellation Order
Bayleton Technical Fungicide (EPA Reg. No. 264-736)

Dear Mr. Tolliver:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable. One copy of the label stamped "Accepted" is enclosed for your records. This label supersedes all labels previously accepted for this product. Should you have any questions or concerns, please contact Tawanda Spears via telephone at 703.308.8050 or e-mail at spears.tawanda@epa.gov.

Sincerely yours,

Tony Kish

Tony Kish
Product Manager (22)
Fungicide Branch
Registration Division (7505P)

Bayleton[®] Technical Fungicide

For use in the manufacture of fungicides.

ACTIVE INGREDIENT:

1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone..... 97.7%

INERT INGREDIENTS:..... 2.3%

100.0%

EPA Reg. No. 264-736

EPA Est. No. 3125-MO-1

STOP - Read the label before use

Keep out of reach of children

WARNING

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF INHALED	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.• Call a poison control center or doctor for further treatment advice.
In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577. Have a product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note To Physician: No specific antidote. Treat symptomatically. The compound does not cause any definite symptoms that would be diagnostic. Poisoning is accompanied by hyperactivity followed by sedation.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic skin reactions in some susceptible individuals. Avoid breathing dust and contact with skin, eyes or clothing. Wash thoroughly with soap and warm water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash separately with soap and hot water before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

ACCEPTED

NOV 2 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg. No. 264-736

71

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into a fungicide, for

(1) the following uses:

- a. Terrestrial Food Crop: pineapple.
- b. Terrestrial Non-Food Crop: pine seed, Christmas trees, turf and ornamentals
- c. Greenhouse Non-Food Crop: ornamentals
- d. Residential Outdoor: ornamentals.

(2) uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and

(3) uses for experimental purposes that are in compliance with USEPA requirements.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ALL LIABILITY BASED ON BREACH OF WARRANTY, NEGLIGENCE, STRICT TORT LIABILITY, OR ANY OTHER THEORY OF LIABILITY FOR CROP DAMAGE OR FAILED EFFICACY RESULTING FROM THE USE OF THIS BAYER CROPSCIENCE PRODUCT AS AN INGREDIENT IN ANY FORMULATION WITH A USE NOT SPECIFICALLY LISTED ON THIS LABEL.

Detailed information on chemical and physical properties and other formulating recommendations for Bayleton are available upon request from Bayer CropScience. Obtain and read this information before undertaking the formulation of Bayleton in order to avoid formulation hazards and insure a satisfactory finished product.

Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency. For specific information on federally registered uses, contact Bayer CropScience. Any variance from the federally registered labeling for products containing Bayleton will have to be supported by data provided by the formulator.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer CropScience Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer CropScience Emergency Response Telephone No. is 1-800-334-7577.

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NET CONTENTS:

PRODUCED FOR



Bayer CropScience

2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

Bayleton Technical (PENDING) 07/11/07

72

EPA Registration Number 84229-5

Page _____ is not included in this copy.

Pages 73 through 74 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☒ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.
- ☐ Internal deliberative information.
- ☐ Attorney-client communication.
- ☐ Claimed confidential by submitter upon submission to the Agency.
- ☐ Personal privacy Information

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATE OUT: December 15, 1997

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF INTEGRATED PRODUCTS: MP** ☐ EP ☒
DP BARCODE No.: 241241 EPA RECEIVED DATE: 12/03/97 REG./File Symbol No.: 3125-319
PRODUCT NAME: Bayleton Technical Fungicide ACTION CODE: 345
COMPANY NAME: Bayer Corp MRID Nos.: None, CSF & label

FROM: Sami Malak, Chemist /S/
Technical Review Branch/RD (7505C)

TO: PM #22 Cynthia Giles-Parker/Maria Rodriguez
Fungicide Branch/Registration Division (7505C)

INTRODUCTION:

With this submission, Bayer Corp. requests review for acceptability product's label to convert to the nominal concentration's concept as per the regulations of PR Notice 91-2.

FINDINGS:

An approved CSF, a basic formulation dated 10/17/96 was included with this submission in support of the conversion from the current label claim of 90% to 97.7% for consistency with that claimed on the CSF.

CONCLUSIONS:

1. At this time, we are unable to accept the label claim of 97.7% bayleton technical fungicide because: (a) the change from 90 to 97.7% is significant; and (b) the limits claimed on the CSF, 99.9 & 90% are wider than what is permitted by the standard limits of 40CFR§158.175.
2. The applicant will need to submit sample analysis, a product chemistry data requirement of GRN 830-1700, to show the actual nominal concentration of bayleton technical. If this information is available in-house, please submit for review.

75

DATE OUT: December 15, 1997

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF INTEGRATED PRODUCTS: MP** ☐ **EP** ☒
DP BARCODE No.: 241241 EPA RECEIVED DATE: 12/03/97 REG./File Symbol No.: 3125-319
PRODUCT NAME: Bayleton Technical Fungicide ACTION CODE: 345
COMPANY NAME: Bayer Corp MRID Nos.: None, CSF & label

FROM: Sami Malak, Chemist /S/
Technical Review Branch/RD (7505C)

TO: PM #22 Cynthia Giles-Parker/Maria Rodriguez
Fungicide Branch/Registration Division (7505C)

INTRODUCTION:

With this submission, Bayer Corp. requests review for acceptability product's label to convert to the nominal concentration's concept as per the regulations of PR Notice 91-2.

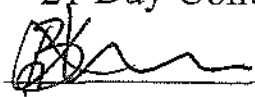
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F. 1A - 21 Day Content Screening Checklist

Experts In-Processing Signature: 

Fee Paid: Yes ☒ No ☐


EPA Reg. Number: 84229-L	EPA Receipt Date: 1/22/08			
	Check List Item	Yes	No	NA
1	Application Form (EPA Form 8570-1) –signed & complete including package type?	<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula (EPA Form 8570-29)			
	a) Is the CSF completely filled out (Boxes 1-21)? Does it add up to 100%	<input checked="" type="checkbox"/>		
	b) After the inerts list is on the web, are all inerts cleared for food and non food proposed uses?			<input checked="" type="checkbox"/>
	c) CAS # provided?	<input checked="" type="checkbox"/>		
3	Certification with Respect to Citation of Data (EPA Form 8570-34)? [Applicable, if submission is not a 100% repack]	<input checked="" type="checkbox"/>		
4	Formulator's Exemption Statement (EPA Form 8570-27)?			
	a) Formulator's Exemption Statement was not addressed because registrant owns/formulates the source of active ingredient in product formulation,	<input checked="" type="checkbox"/>		
	b) if so, was a generic data matrix included?	<input checked="" type="checkbox"/>		
5	Data Matrix (EPA Form 8570-35) [Applicable, if submission is not a 100% repack]			
	a) Selective Method?			
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay	<input checked="" type="checkbox"/>		
	c) Public copy of Matrix provided? See PR Notice 98-5	<input checked="" type="checkbox"/>		
6	Is Label Included? (5 copies)			
7	Letter of Authorization for exclusive use only?	<input checked="" type="checkbox"/>		
8	Required Data and or data waivers submitted?	<input checked="" type="checkbox"/>		
	a) Which study(s) is missing? List them below			<input checked="" type="checkbox"/>
9	CRP Certification Statement			<input checked="" type="checkbox"/>
10	86-5 Rejection List?			<input checked="" type="checkbox"/>
11	Notice of Filing included with petitions?			<input checked="" type="checkbox"/>
	Comments:			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date Jan. 14, 2008			EPA Reg. No./File Symbol 84229-		Page 1 of 5
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Triadimefon Technical		
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Requirements					
830.1550	Product Identity and Composition	Volume 1	Tide International USA, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Tide International USA, Inc.	OWN	
830.1620	Description of Production Process	Volume 1	Tide International USA, Inc.	OWN	
830.1650	Description of Formulation Process				Not required ¹
830.1670	Discussion of Formation of Impurities	Volume 1	Tide International USA, Inc.	OWN	
830.1700	Preliminary Analysis	Volume 2 Volume 3	Tide International USA, Inc.	OWN	
830.1750	Certified Limits	Volume 1	Tide International USA, Inc.	OWN	
830.1800	Enforcement Analytical Method	Volume 1	Tide International USA, Inc.	OWN	
830.6302	Color	Volume 4	Tide International USA, Inc.	OWN	
830.6303	Physical State	Volume 4	Tide International USA, Inc.	OWN	
830.6304	Odor	Volume 4	Tide International USA, Inc.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 5	Tide International USA, Inc.	OWN	Waiver ²
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 4	Tide International USA, Inc.	OWN	
830.6315	Flammability	Volume 5	Tide International USA, Inc.	OWN	Waiver ³
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 14, 2008

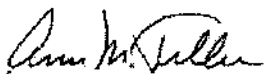
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

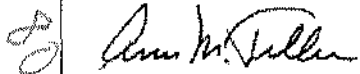
Date Jan. 14, 2008			EPA Reg. No./File Symbol 84229-	Page 2 of 5	
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Triadimefon Technical		
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	Volume 5	Tide International USA, Inc.	OWN	Waiver ⁴
830.6317	Storage Stability	Volume 5	Tide International USA, Inc.	OWN	PRN 92-5 ⁵
830.6319	Miscibility				Not required ⁶
830.6320	Corrosion Characteristics	Volume 5	Tide International USA, Inc.	OWN	PRN 92-5 ⁵
830.6321	Dielectric Breakdown Voltage				Not required ⁷
830.7000	pH	Volume 4	Tide International USA, Inc.	OWN	
830.7050	UV/Visible Absorption	Volume 4	Tide International USA, Inc.	OWN	
830.7100	Viscosity	Volume 5	Tide International USA, Inc.	OWN	Waiver ⁸
830.7200	Melting Point/Melting Range	Volume 4	Tide International USA, Inc.	OWN	
830.7220	Boiling Point/Boiling Range				Not required ⁹
830.7300	Density/Relative Density/Bulk Density	Volume 4	Tide International USA, Inc.	OWN	
830.7370	Dissociation Constants in Water	Volume 5	Tide International USA, Inc.	OWN	Waiver ¹⁰
830.7520	Particle Size, fiber length, and diameter distribution	Volume 5	Tide International USA, Inc.	OWN	Waiver ¹¹
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 5	Tide International USA, Inc.	PL	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 14, 2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

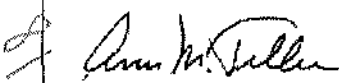
Date Jan. 14, 2008			EPA Reg. No./File Symbol 84229-		Page 3 of 5
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Triadimefon Technical		
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 5 Volume 4	Tide International USA, Inc.	PL OWN	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 5	Tide International USA, Inc.	PL	
870.1100	Acute Oral Toxicity: Rat	Volume 6	Tide International USA, Inc.	OWN	
870.1200	Acute Dermal Toxicity: Rat	Volume 7	Tide International USA, Inc.	OWN	
870.1300	Acute Inhalation Toxicity: Rat	Volume 8	Tide International USA, Inc.	OWN	
870.2400	Primary Eye Irritation: Rabbit	Volume 9	Tide International USA, Inc.	OWN	
870.2500	Primary Dermal Irritation	Volume 10	Tide International USA, Inc.	OWN	
870.2600	Dermal Sensitization	Volume 11	Tide International USA, Inc.	OWN	
Tide International USA, Inc. will make offers-to-pay to the following companies on the September 30, 2007 Data Submitters List for Triadimefon					
Triadimefon Generic Data Requirements					
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer CropScience LP	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer Environmental Science	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 14, 2008

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WASHINGTON, D.C. 20460

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DATA MATRIX

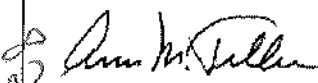
Date Jan. 14, 2008			EPA Reg. No./File Symbol 84229-		Page 4 of 5
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Triadimefon Technical		
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer Corp.	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		The Andersons Lawn Fertilizer Division	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Woodstream Corp.	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Spray Drift Task Force	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Outdoor Residential Exposure Task Force LLC	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Agricultural Reentry Task Force	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Bayer Advanced	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		FIFRA Endangered Species Task Force LLC	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Agricultural Handlers Exposure Task Force	PAY	
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		Residential Exposure Joint Venture	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 14, 2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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WASHINGTON, D.C. 20460

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DATA MATRIX

Date Jan. 14, 2008			EPA Reg. No./File Symbol 84229-	Page 5 of 5	
Applicant's/Registrant's Name & Address Tide International USA, Inc. 21 Hubble Irvine, CA 92618			Product Triadimefon Technical		
Ingredient Triadimefon (CAS No. 43121-43-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Triadimefon Generic Data Requirements	Cite-All utilized by Tide International USA, Inc. for Triadimefon generic data requirements		U.S. Triazole Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date Jan. 14, 2008

Endnotes for Data Matrix for Triadimefon Technical

- ¹ **830.1650** - These data are not required for the registration of a technical product. See **830.1620** for production process information.
- ² **830.6313** - Tide International USA, Inc. will not be packaging Triadimefon Technical in metal containers, nor is it expected to come into contact with metals or metal ions during its storage. In addition, Triadimefon Technical is not expected to be subjected to temperatures greater than 50°C during its production or storage. Therefore, Tide International USA, Inc. seeks a waiver from the requirement for these data.
- ³ **830.6315** - Tide International USA, Inc. requests a waiver from the requirement for flammability for Triadimefon Technical based on the fact that this technical is a solid and is not expected to be flammable. Please refer to the Confidential Statement of Formula for Triadimefon Technical.
- ⁴ **830.6316** - Tide International USA, Inc. requests a waiver from the requirement of this study. Triadimefon Technical does not have the chemical bonds or functional groups associated with explosive chemicals. Please refer to the Confidential Statement of Formula for additional information on the composition of Triadimefon Technical.
- ⁵ **830.6317 and 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Tide International USA, Inc. agrees to conduct these studies if required and requests that the studies be made a condition of registration.
- ⁶ **830.6319** - These data are required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. Triadimefon Technical is a solid and not an emulsifiable liquid. Therefore, this data requirement is not applicable to Triadimefon Technical.
- ⁷ **830.6321** - These data are required if the end use product is to be used around electrical equipment. Triadimefon Technical is not an end use product and therefore this data requirement is not applicable.
- ⁸ **830.7100** - These data are required when the product is a liquid. Triadimefon Technical is a solid. Therefore, this data requirement is not applicable to Triadimefon Technical.
- ⁹ **830.7220** - Boiling point data are only required for liquids. Triadimefon Technical is a solid. Therefore, this data requirement is not applicable to Triadimefon Technical.
- ¹⁰ **830.7370** - Tide International USA, Inc. is seeking a waiver for the dissociation constant for Triadimefon Technical because the chemical does not contain any functionality that would dissociate. The EPA Reregistration Eligibility Decision document for triadimefon listed this data requirement as not being applicable (Ref.: Reregistration Eligibility Decision for Triadimefon and Tolerance Reassessment for Triadimenol, August 2006, Appendix B-1, page 85).
- ¹¹ Tide International USA, Inc. is seeking a waiver for this data requirement for Triadimefon Technical because the product is not water insoluble nor is it a fibrous material.

PRIA fee has been pre-paid.

Copy of check/pay.gov
receipt enclosed.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 24, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-388811
EPA File Symbol or Registration Number: 84229-L
Product Name: TRIADIMEFON TECHNICAL
EPA Receipt Date: 22-Jan-2008
EPA Company Number: 84229
Company Name: TIDE INTERNATIONAL, USA, INC.

JANELLE KAY
TIDE INTERNATIONAL, USA, INC.
C/O PYXIS REGULATORY CONSULTING, INC
4110 136TH ST. NW
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Owens".

Front End Processing Staff
Information Technology & Resources Management Division

85

Fee for Service

823115W~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

22

Receipt No.

S-

823115

EPA File Symbol/Reg. No.

84229L

Pin-Punch Date:

1/22/2008



This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R310

Amount Due: \$ 4,360

Parent/Child Decisions:



Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer:

[Signature]

Date: 1/24/08

Remarks:

Technical + Impurities only. No inerts for review.

A. Debesari

1/28/08

86

FEE FOR SERVICE

S: 823115

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 84229 TIDE INTERNATIONAL, USA, INC. V

Risk Manager: Registration Division, Risk Management Team 22

Product #: 84229-L Product Name: TRIADIMEFON TECHNICAL

Override:

Me Too Section3: 264-736 Me Too Product Name: BAYLETON TECHNICAL FUNGICIDE

Application Date: 15-Jan-2008 icl OPP Rec'd Date: 22-Jan-2008 icl

Front End Date: 23-Jan-2008 icl Risk Manager Send Date: icl

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Application for registration for a new technical product

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Study

Online Payment

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 24UGL9V8

Agency Tracking ID: 74038552553

Transaction Date and Time: 01/21/2008 14:21 EST

Payment Summary

Address Information	Account Information	Payment Information
Account Holder Name: Der I Wang Billing Address: 2007A, Via Mariposa West Billing Address 2: City: Laguna Woods State / Province: CA Zip / Postal Code: 92637 Country: USA	Card Type: American Express Card Number: *****1006 Expiration Date: 5 / 2010 Decision Number: Registration Number:	Payment Amount: \$4,360.00 Transaction Date and Time: 01/21/2008 14:21 EST

Do you want to a new plastic card?

89



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

115

Application for Pesticide - Section I

1. Company/Product Number 84229- L	2. EPA Product Manager T. Kish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tide International USA, Inc./Triadimefon Technical	PM# 22	
5. Name and Address of Applicant (Include ZIP Code) Tide International USA, Inc. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. 264-736 (formerly 3125-319) Product Name Bayleton Technical Fungicide	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R310 (46: New manufacturing use product) because it is an application for registration (using the cite-all method of support) for a new technical product substantially similar to a currently registered product. The fee which has been paid is \$4360 and the decision timeline is 6 months.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
If "Yes" Unit Packaging wgt. No. per container			II "Yes" Package wgt. No. per container	<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) lined HOPE drum	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 50 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann Tillman	Title Agent	Telephone No. (Include Area Code) (253) 853-7369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Ann Tillman	5. Date 1/15/08	

90

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

Phone: 253-853-7369
Fax: 253-853-5516
www.PyxisRC.com

Jan. 15, 2008

OVERNIGHT DELIVERY

Tony Kish (PM 22)
Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Dear Mr. Kish,

RE: Tide International USA, Inc.
Triadimefon Technical (EPA Reg. No. 84229-)
Application for New Pesticide Registration

On behalf of Tide International USA, Inc., we are submitting an application for registration of Triadimefon Technical. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Five (5) Copies of the Proposed Labeling
4. Certification with Respect to Citation of Data (EPA Form 8570-34)
5. Agency Internal Use Copy of the Data Matrix
6. Public File Copy of the Data Matrix
7. Copy of PRLA payment
8. Letter of Authorization
9. Product Specific Data (3 copies of each report):

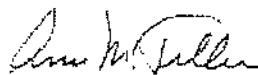
Volume 1	830.1550, 830.1600, 830.1620, 830.1670, 830.1750, 830.1800	Tillman, A.M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits and Enforcement Analytical Method for Triadimefon Technical. <i>Contains Confidential Business Information</i>
Volume 2	830.1700	Kaminsky, M. Triadimefon Technical. Preliminary Analysis. <i>Contains Confidential Business Information</i>
Volume 3	830.1700	Kaminsky, M. Triadimefon Technical: Validated Analytical Method to Analyze an Impurity of Toxicological Concern in a Technical Grade Material. <i>Contains Confidential Business Information</i>

Volume 4	830.6302, 830.6303, 830.6304, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300, 830.7840	Kaminsky, M. Triadimefon Technical. Product Chemistry.
Volume 5	830.6313, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, 830.7370, 830.7520, 830.7550- 7570, 830.7840- 7860, 830.7950	Tillman, A. Waiver Request for Certain Data Requirements for Triadimefon Technical.
Volume 6	870.1100	Kuhn, J. O. Triadimefon Technical Acute Oral Toxicity Study (UDP) in Rats.
Volume 7	870.1200	Kuhn, J. O. Triadimefon Technical Acute Dermal Toxicity Study in Rabbits.
Volume 8	870.1300	Crutchfield, V. Triadimefon Technical Acute Inhalation Toxicity Study in Rats.
Volume 9	870.2400	Kuhn, J. O. Triadimefon Technical Acute Eye Irritation Study in Rabbits.
Volume 10	870.2500	Kuhn, J. O. Triadimefon Technical Acute Dermal Irritation Study in Rabbits.
Volume 11	870.2600	Kuhn, J. O. Triadimefon Technical Skin Sensitization Study in Guinea Pigs.

We would like to note that Tide International USA, Inc. is using the cite-all method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Tide International USA, Inc. submitted notices of intent to apply and offers to pay to all companies on the September 30, 2007 Data Submitter's List. This action falls under PRIA category R310 (46: New manufacturing product) because it is an application for registration for a technical product substantially similar to a currently registered product. The fee for this action is \$4,360 and has been paid. The decision timeline is 6 months.

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, Ann@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Tide International USA, Inc. c/o Pyxis Regulatory Consulting 4110 1st St. NW Gg Harbor, WA 98112	EPA Registration Number/File Symbol 84229-
Active ingredient(s) and/or representative test compound(s) Triadimefon	Date Jan. 15, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non-food crop; Greenhouse non-food	Product Name Triadimefon Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to use that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid in exchange for use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ann M. Tittman</i>	Date Jan. 15, 2008	Typed or Printed Name and Title Ann M. Tittman, Agent
------------------------------------	-----------------------	--

93



TIDE INTERNATIONAL USA INC.

21 Hubble, Irvine, CA. 92618, USA
Tel: 1-626-303-0133 Fax: 1-626-303-0188

February 20, 2003

To Whom It May Concern:

RE: Letter of Authorization

Please let this letter serve to notify you that Pyxis Regulatory Consulting, Inc. is authorized to represent Tide International Co., Ltd (EPA Company Number 69845) before the US Environmental Protection Agency and California Department of Pesticide Regulation in all matters regarding our registrations and applications for registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Der-I Wang, Ph. D.
Vice President, Marketing

EPA Registration Number 84229-5

Page _____ is not included in this copy.

Pages 95 through 96 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☒ A draft product label.
- ☒ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.
- ☐ Internal deliberative information.
- ☐ Attorney-client communication.
- ☐ Claimed confidential by submitter upon submission to the Agency.
- ☐ Personal privacy Information

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.